

REMARKS

Applicants respectfully request reconsideration of the application, as amended, in view of the following remarks.

Claims 1-9 have been canceled in favor of new Claims 10-18 which are based on original Claims 1-9. New Claims 10 to 18 are directed to transdermal absorption preparation. New independent Claim 10 further limits the component (c) lauromacrogol to “lauryl ethers with 2 to 25 mol ethylene oxide addition” based on the description of page 4, lines 17 to 19 of the originally-filed specification and the component (d) to “loperamide hydrochloride or lidocaine” based on the results of the Examples.

No new matter is believed to have been added by entry of this amendment. Entry and favorable reconsideration are respectfully requested.

Upon entry of this amendment Claims 10-18 will now be active in this application.

The rejection of Claims 1-9 under 35 U.S.C. § 112, 1st paragraph, and the rejection of Claims 5 and 7-8 under 35 U.S.C. § 112, 2nd paragraph, are obviated by new Claims 10-18. In **new Claim 10** component (c) is defined as lauromacrogol which is lauryl ethers with 2 to 25 mol ethylene oxide addition, and component (d) is defined as loperamide hydrochloride or lidocaine. The new dependent claims have also been revised compared to the original dependent claims thereby obviating the rejections. Thus, these rejections should be withdrawn.

Furthermore, all inventors designated in this application were employees of the Assignee and under obligation to assign the results of their research to the Assignee at the time the invention was made. Thus, all claims were commonly owned at the time the present invention was made.

The present invention as set forth in **new Claim 10** relates to a transdermal absorption preparation, comprising:

- (a) propylene glycol,
- (b) a polyol fatty acid ester,
- (c) lauromacrogol which is selected from the group consisting of lauryl ethers with 2 to 25 mol ethylene oxide addition, and
- (d) loperamide hydrochloride or lidocaine.

The rejection of Claims 1-7 and 9 under 35 U.S.C. § 103(a) over Ikeda et al is respectfully traversed.

Ikeda et al. disclose propylene glycol, polyol fatty acid ester, lauromacrogol and the like for use as a copolymer solubilizer.

However, Ikeda et al. fail to disclose or suggest use of lauromacrogol with ethylene oxide addition of specific mol number, or use of such lauromacrogol in combination with propylene glycol and polyol fatty acid ester. Further, Ikeda et al. do not disclose or suggest that propylene glycol and the like used as a copolymer solubilizer have transdermal absorption promotion effect.

Furthermore, there is no description of a substance which enhances transdermal absorbency of loperamide hydrochloride or lidocaine.

In view of the above, use of lauromacrogol with ethylene oxide addition of specific mol number in combination with propylene glycol and polyol fatty acid ester for the purpose of enhancing transdermal absorbency of loperamide hydrochloride or lidocaine is not obvious in view of Ikeda et al.

Therefore, the rejection of Claims 1-7 and 9 under 35 U.S.C. § 103(a) over Ikeda et al is believed to be unsustainable as the present invention is neither anticipated nor obvious and withdrawal of this rejection is respectfully requested.

In addition, the rejection of Claims 1-9 under 35 U.S.C. § 103(a) over El Khoury is respectfully traversed.

El Khoury solely discloses topical transdermal enhancing agents which are commonly described in text books, and such disclosure does not lead to conceiving the use of lauromacrogol with ethylene oxide addition of specific mol number in combination with polypylene glycol and polyol fatty acid ester. Further, solely from the description of generally known topical transdermal enhancing agents, it is not be possible to routinely determine suitable transdermal enhancing preparations for loperamide hydrochloride or lidocaine, both being difficult to be absorbed transdermally in known transdermal preparations due to their relatively high lipophilic property.

Therefore, the rejection of Claims 1-9 under 35 U.S.C. § 103(a) over El Khoury is believed to be unsustainable as the present invention is neither anticipated nor obvious and withdrawal of this rejection is respectfully requested.

This application presents allowable subject matter, and the Examiner is kindly requested to pass it to issue. Should the Examiner have any questions regarding the claims or otherwise wish to discuss this case, he is kindly invited to contact Applicants' below-signed representative, who would be happy to provide any assistance deemed necessary in speeding this application to allowance.


Respectfully submitted,

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